

AMENDMENT UNDER 37 C.F.R. § 1.111
U.S. Application No.: 09/848,225

REMARKS

Review and reconsideration on the merits are requested.

Claims 1-11 are pending.

Claims 1 and 7 have been amended. Claims 1 and 7, as amended, are directed to a clear aqueous ceramide composition, which is not irritating to the skin and a method of making thereof, respectively. Support for the amendments can be found on page 3, line 17, through page 4, line 1.

Claim 5 has been amended to read as an independent claim by incorporating the elements of independent claim 1.

Applicants first address claim rejections - 35 U.S.C. § 112. The Examiner maintains that claims 5 and 6 are indefinite since claim 1 recites the transitional phrase "consisting essentially of" yet claim 5 attempts to include another active ingredient which would materially change the nature of the composition. This rejection is respectfully traversed.

Simply stated, the additional components of claim 5, which is now rewritten in independent form, do not substantially change the effects of the composition of claim 1. In more detail, the additional components defined in claim 5 (sterols, polyhydric alcohols) do not substantially change the effects of the composition of claim 1 (clear aqueous - transparent). From Table 1, it is clear that the effects of a clear aqueous (transparent) according to the present invention are exhibited with the components of claim 1 (Example 1). Examples 2-4 are add polyhydric alcohols as additional components and Example 5 adds sterols as an additional component. Examples 2 to 5 sufficiently show the effects of the present invention (clear aqueous

AMENDMENT UNDER 37 C.F.R. § 1.111
U.S. Application No.: 09/848,225

- transparent) and thus the additional components defined in claim 5 do not substantially change the effects of the composition of claim 1.

However, at the same time, Applicants respectfully submit that "consisting essentially of" does exclude the ionic surfactant of Nakamura. Even if addition of an ionic surfactant would not change the clear aqueous nature of the composition of the present invention, quite clearly such would not beneficially effect the composition of the present invention. See in this regard, Table 3, Application Example 1 where the addition of sodium POE(4) lauryl ether phosphate provides no beneficial effects to the present invention with respect to the clear aqueous nature thereof. However, as described in the present specification, ionic surfactants can lead to the danger of skin irritation (specification, page 3, lines 17-19), a factor which quite clearly would be viewed as undesirable by one of ordinary skill in the art. Therefore, as a result of the skin irritation associated with ionic surfactants, one skilled in the art would consider ionic surfactants to materially affect the claimed composition.

Withdrawal is requested.

Applicants now turn to the only art rejection in this case.

Claims 1-11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 5,294,444 Nakamura et al (Nakamura) in combination with WO 98/27958 Kaneko et al (Kaneko).

This rejection is respectfully traversed.

AMENDMENT UNDER 37 C.F.R. § 1.111
U.S. Application No.: 09/848,225

Applicants note that, as discussed above, claims 1 and 7 have been amended and recite a clear aqueous ceramide composition, which is not irritating to the skin and a method of making thereof, respectively.

The Examiner's position on the prior art is well set forth in the Action and is not repeated here except as necessary to an understanding of Applicants' traversal which his now presented.

Applicants respectfully submit that even if one of ordinary skill in the art would be led to combine Nakamura and Kaneko, one of ordinary skill in the art would not be led to the present invention. Specifically, Nakamura is directed to a combination of 1) an amphipathic lipid (which may include a ceramide), 2) a non-ionic surfactant, 3) an ionic surfactant, and 4) an aqueous medium. Aqueous medium 4) substantially includes polyhydric alcohols (e.g., glycerol and ethanol) and alcohols.

In distinction, the present invention relates to a combination of 1) a specific ceramide, 2) a long-chain fatty acid, 3) a nonionic surface active agent, and 4) water. Water 4) is water itself which does not include other components.

As is clear from Example 1 in the present specification, the present invention achieves aqueous clear (transparent) state characteristics by the combination of these four components. Comparing the present invention to Nakamura, Nakamura is different from the present invention in that ionic surfactants and polyhydric alcohols or alcohols are essential. In the present invention, ionic surfactants are not essential (rather, the use of ionic surfactants may result in skin irritation as described above), and polyhydric alcohols or alcohols are not essential.

AMENDMENT UNDER 37 C.F.R. § 1.111
U.S. Application No.: 09/848,225

Accordingly, the present invention has superiority in that costs and load on the environment can be reduced.

In the Examples of Nakamura, it is disclosed that the products obtained are all transparent or semitransparent liquids. From this language, it is not clear whether the products were transparent or semitransparent. It could be concluded that a semitransparent product was obtained but it cannot be concluded with certainty that a transparent product was obtained. In the Examples of the present specification, all products are transparent (O), except Example 2 wherein ceramide was added in an amount of 3% and that product was almost transparent (O). It is thus quite clear that using the combination of the present invention, the desired result of obtaining a clear aqueous ceramide composition is achieved. It is problematic whether such desired result is achieved in Nakamura.

Since Applicants traverse with respect to Nakamura, Applicants respectfully submit that even if the ceramide of Kaneko were to be used in the compositions of Nakamura, the present invention would not be rendered obvious.

With respect to **Response to Arguments**, Applicants believe that they have responded to the Examiner's position regarding claims 5 and 6 and the teaching of Nakamura.

AMENDMENT UNDER 37 C.F.R. § 1.111
U.S. Application No.: 09/848,225

Withdrawal of all art rejections and allowance is requested.

Respectfully submitted,

Peter Olexy / Patrick Gally Jr.
Reg. No. 54,109

Peter D. Olexy, P.C.
Registration No. 24,513

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: May 19, 2004